

Intracorneal Ring Segment Implantation in Corneas with Post-Laser In Situ Keratomileusis Keratectasia

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Purpose: To evaluate the refractive and aberrometric changes in corneas with post-LASIK keratectasia implanted with intracorneal ring segments (ICRS) during a 2-year follow-up.

Design: Retrospective, consecutive case series.

Participants: Thirty-four eyes of 25 patients (age range, 20–59 years) with post-LASIK ectasia were included. Ectasia was diagnosed by slit-lamp appearance of corneal thinning, unstable topographic steepening, progressive corneal thinning on ultrasonic pachymetry, decreased visual acuity, and unstable refraction.

Methods: Intracorneal ring segment implantation was performed in all cases by 2 surgeons from 2 different ophthalmologic centers with the aim of correcting the spherocylindrical error and improving the visual quality. Corneal tunnels were created by means of mechanical dissection in 20 eyes and femtosecond laser technology in 14 eyes. Intacs (Addition Technology, Inc, Fremont, CA) were inserted in 24 eyes, and KeraRings (Mediphacos, Belo Horizonte, Brazil) in 10 eyes. In all cases a follow-up of 12 months was completed, with a total of 15 eyes examined 24 months after surgery.

Main Outcome Measures: Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), refraction, keratometry, and corneal aberrations.

Results: Uncorrected visual acuity did not improve after surgery ($P = 0.17$). Best spectacle-corrected visual acuity increased significantly at 6 months ($P = 0.02$). Some 38.89% of eyes gained 2 or more lines of BSCVA at 6 months, and this percentage increased to 60% at 24 months. There was a nonsignificant reduction of sphere at 6 months ($P = 0.28$). Manifest cylinder was reduced significantly during the postoperative follow-up ($P = 0.05$, preoperative to 6 months; $P = 0.04$, 6–12 months). The cornea was on average flatter at 6 months ($P < 0.01$), with a posterior nonsignificant regression of the achieved flattening ($P = 0.73$). In regard to corneal aberrations, a statistically significant reduction was found in coma-like root mean square (RMS) ($P = 0.03$) after surgery. Segment ring explantation was performed in 6 eyes, and ring reposition was performed in 2 eyes. The apical curvature gradient was significantly higher in the group of explanted eyes ($P = 0.03$).

Conclusions: Intracorneal ring segment implantation is a useful option for the treatment of coma-like aberrations and astigmatism in post-LASIK corneal ectasia.

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Corneal keratectasia is a serious complication of LASIK surgery^{1–9} and is especially observed in corneas significantly ablated centrally with the excimer laser (high myopes).^{2–5} This was first described by Seiler et al^{8,9} in 1998. It consists of a progressive corneal steepening, usually inferiorly, with an increase in all ocular aberrations, and loss of uncorrected visual acuity (UCVA) and frequently best spectacle-corrected visual acuity (BSCVA).² This ectatic disorder has an estimated incidence that ranges from 0.04% to 0.6%.¹⁰ The specific mechanism resulting in these corneal alterations still remains unknown.^{2,4,11} The corneal weakening induced by the excimer laser ablation seems to have a significant role in the development of this complication.^{4,12,13} Several risk factors have been identified for the development of post-LASIK ectasia, such as the presence of a large preoperative myopic refractive error, a low residual stromal bed

thickness,^{2,4,10,11,14} a small modulus of elasticity,¹⁵ or some corneal topographic abnormalities.^{2,4,10,11,14}

A variety of therapeutic options have been described for the post-LASIK keratectasia, such as rigid gas permeable contact lenses,^{2,16} intracorneal ring segment (ICRS) implantation,^{13,17–24} or corneal transplantation.^{2,16} The management of these patients must include visual rehabilitation because the visual function is devastated as the result of the significant increase in all ocular aberrations. The control of the keratectasia progression is another objective when treating these eyes. ICRS implantation has been proved effective in improving visual acuity,¹ reducing the refractive error and keratometry.^{17–24} In addition, this kind of treatment has been demonstrated to be useful to prevent the need for keratoplasty and the progression of the iatrogenic cone.¹⁸

The addition of extra material at the normal corneal mid-periphery induces a displacement of the local anterior surface. This displacement induces a steepening of the peripheral cornea and a flattening of the central portion of the anterior cornea because of the morphologic structure of corneal lamellae.²⁵ If changes induced by ICRS in the normal cornea are assumed to be similar in the post-LASIK ectatic cornea, these segments would minimize the corneal protrusion. As a consequence, significant changes in refraction and corneal regularity would be induced. This potential corneal regularization would induce a significant reduction of corneal aberrations and then an improvement of BSCVA. Although a best-corrected visual improvement was reported by previous authors in eyes with post-LASIK ectasia and ICRS, aberrometric changes have still not been analyzed and reported.

To the best of our knowledge, this study is the first to analyze the corneal aberrometric changes in post-LASIK ectatic corneas after ICRS implantation. In addition, we report in this study the largest series of cases with post-LASIK ectasia and treated with ICRS. The objective of the present study was to analyze the refractive and corneal aberrometric changes in a medium to long-term follow-up after the implantation of ICRS in eyes with post-LASIK corneal ectasia. Refractive and aberrometric stability, as well as late sequelae, were carefully analyzed. In addition, factors related to a good prognosis were identified.

Patients and Methods

Patients

A retrospective analysis of outcomes of all patients who underwent ICRS implantation for the management of post-LASIK ectasia from September 2000 to June 2007 in 2 different Spanish ophthalmologic centers (Visum Alicante and Visum Sevilla) was performed. A total of 37 eyes with post-LASIK ectasia were diagnosed and examined during this period, some of them from our clinic and others referred by other centers. In all cases the implantation of ICRS was indicated, but finally 3 patients did not undergo operation because they preferred to wait and see the evolution of the case. Thirty-four consecutive eyes of 25 patients who had undergone 1 or more previous LASIK procedures and with post-LASIK corneal ectasia (17 unilateral and 8 bilateral) were finally included. Ectasia was diagnosed by slit-lamp appearance of corneal thinning, unstable topographic steepening (>1 D for each 6-month follow-up), progressive corneal thinning on ultrasonic pachymetry, decreased visual acuity, and unstable refraction (>0.5 D for spherical equivalent [SE] for each 6-month follow-up).¹⁸

A comprehensive examination was performed in all cases before the ICRS implantation, which included Snellen UCVA (decimal notation), Snellen BSCVA (decimal notation), manifest refraction, slit-lamp biomicroscopy, Goldman tonometry, fundus evaluation, ultrasonic pachymetry, and corneal topographic analysis. Because topographic data were collected from different periods and 2 different centers, a total of 3 different corneal topography systems were used for corneal examination: CMS 100 Topometer (G. Rodenstock Instrument GmbH, Ottobrunn, Germany), Costruzione Strumenti Oftalmici (CSO, Firenze, Italy), and Orbscan IIz system (Bausch & Lomb, Rochester, NY). The first 2 devices are Placido-based systems, and the Orbscan II is a combined scanning-slit and Placido-disc topography system. Although

the agreement between these specific devices has not been reported, Orbscan and Placido-based devices have been proved to provide similar accuracy and precision on calibrated spherical test surfaces.²⁶ In this study, the following topographic data were evaluated and recorded with all corneal topographic devices: the corneal dioptric power in the flattest meridian for the 3-mm central zone (K1), corneal dioptric power in the steepest meridian for the 3-mm central zone (K2); mean corneal power in the 3-mm zone (KM); and inferosuperior asymmetry index (ISAI), calculated as the difference between the dioptric power at 3 mm below and above the corneal geometric center. Additional topographic parameters were analyzed and recorded in patients examined with the CSO topographic system (15 eyes): the corneal astigmatism in the 3-mm zone (AST3), corneal astigmatism in the 6-mm zone (AST6), mean asphericity for a corneal area of 4.5-mm diameter (Q45), mean asphericity for a corneal area of 8-mm diameter (Q8), apical keratometry, and apical curvature gradient (ACG).

All patients had undergone LASIK surgery at least 12 months before ICRS implantation. During the process of consent for this surgery, consent was taken to later include clinical information in scientific studies. Ethical board committee approval of our institution (Visum Instituto Oftalmológico de Alicante) was obtained for this investigation. In all cases, a follow-up of 12 months or more was completed, with a total of 15 eyes examined 24 months after surgery.

Corneal Aberrations of Anterior Surface

Corneal aberrometry was also recorded and analyzed only in those patients examined in all visits with the CSO topography system (15 eyes), because this device was the only one with the capability to calculate directly this specific information. This topography system analyzes a total of 6144 corneal points of a corneal area enclosed in a circular annulus defined by an inner radius of 0.33 and an outer radius of 10 mm with respect to corneal vertex. The software of the CSO, the EyeTop2005 (CSO), automatically performs the conversion of corneal elevation profile into corneal wavefront data using the Zernike polynomials with an expansion up to the seventh order. In this study, the aberration coefficients and root mean square (RMS) values were calculated for a 6-mm pupil in all cases. The following parameters were analyzed and recorded: total RMS, RMS for corneal astigmatism, primary coma RMS (computed for the Zernike terms $Z_3^{\pm 1}$), coma-like RMS (computed for third, fifth, and seventh-order Zernike terms), spherical-like RMS (computed for fourth and sixth-order Zernike terms), and higher-order residual RMS (computed considering all Zernike terms except those corresponding with primary coma and spherical aberration). The corresponding Zernike coefficient for primary spherical aberration (Z_4^0) was also reported with its sign.

Surgery

Surgical procedures were performed by 2 surgeons, one from Visum Alicante (JLA) and the other from Visum Sevilla (AUM). In all cases, an antibiotic prophylaxis before surgery consisting of topical ciprofloxacin (Oftecilox; Alcon Cusí, Barcelona, Spain) to be applied every 8 hours for 2 days was prescribed. All procedures were performed under topical anesthesia.

Corneal tunnelization for ring segment insertion was performed by mechanical dissection in 20 eyes (58.8%) and by femtosecond laser technology in 14 eyes (41.2%). Incision was located on the steepest meridian of the anterior corneal surface in all patients except 4 (11.8%). A tunnel with an inner and outer diameter of 6.6 and 7.8 mm, respectively, was always planned for Intacs (Addition Technology, Inc, Fremont, CA) implantation, and an inner and outer diameter of 4.8 mm and 5.7 mm, respectively, was planned

Table 1. Implantation Nomogram Used for Intacs in this Study: Number of Segments and Their Thicknesses Were Selected According to the Corneal Topographic Pattern

Corneal Topography Pattern	Indication
Steepening area not involving the 180-degree meridian of the cornea (inferior cone)	1 segment of 0.45-mm thickness
Steepening extending at least 1 mm above and beyond the 180-degree meridian (central cone)	2 segments: 0.45-mm thickness segment inferiorly and 0.25-mm thickness segment superiorly

Intacs; Addition Technology, Inc, Fremont, CA.

for KeraRings (Mediphacos, Belo Horizonte, Brazil) implantation. No complications occurred intraoperatively.

The mechanical surgical procedure was initiated by marking a reference point for centration (pupil center) and performing a radial incision of approximately 1.8 mm in length. After this, a calibrated diamond knife was set at approximately 70% of the mean corneal thickness determined by ultrasonic pachymetry. From the base of the incision, pocketing hooks were used to create corneal pockets on each side of the incision, taking care to maintain a uniform depth. A device containing a semiautomated suction ring was placed around the limbus, guided by the previously marked reference point on the cornea. Two semicircular dissectors were placed sequentially into the lamellar pocket to be steadily advanced by a rotational movement (counterclockwise and clockwise dissectors).²⁷ In the femtosecond laser-assisted surgical procedure, the disposable glass lens of the laser system was first applanated to the cornea to fixate the eye and help maintain a precise distance from the laser head to the focal point.²⁸ Then, a continuous circular stromal tunnel was created at approximately 80% of corneal depth (if this depth was $<400\ \mu\text{m}$; if not, a channel was dissected exactly at $400\ \mu\text{m}$) within 15 seconds with no corneal manipulation.²⁸ The 30-kHz IntraLase femtosecond system was always used (IntraLase Corp, Irvine, CA).

Intacs were inserted in 24 eyes (70.6%), and KeraRings were inserted in 10 eyes (29.4%). Intacs were implanted using the femtosecond technology in only 4 eyes (20%), and KeraRings were implanted in all cases using this technology. Intacs were indicated if SE was less than $-2\ \text{D}$ to induce small modifications in refraction. Selection of the number of Intacs (1 or 2) to implant and thicknesses was performed following the criteria defined previously by our research group,²⁷ which is based on corneal topog-

raphy pattern (Table 1). For KeraRings, the nomogram defined by the manufacturer²⁸ was followed for defining the modality of implant (Table 2). In this study, all KeraRings that were implanted had an arc length of 160 degrees. Only 1 ring segment was implanted in 16 eyes (47.1%), whereas 2 segments were necessary in 18 eyes (52.9%).

Topical tobramycin and dexamethasone eye drops (TobraDex; Alcon Laboratories, Inc, Fort Worth, TX) were used postoperatively every 6 hours for 1 week and stopped. Topical lubricants were also prescribed to be applied every 6 hours for 1 month (Systane, Alcon Laboratories, Inc).

Follow-up Evaluation

Postoperative visits were scheduled for the first postoperative day and for months 1, 3, 6, 12, and 24 postoperatively. On the first postoperative day, UCVA measurement and slit-lamp examination (ICRS position and corneal integrity) were performed. In the remaining postoperative visits the measurement of UCVA and BSCVA, manifest refraction, slit-lamp biomicroscopy, and corneal topographic analysis were performed. Follow-up ranged from 12 to 24 months.

Statistical Analysis

The Statistical Package for the Social Sciences version 10.1 for Windows (SPSS, Chicago, IL) was used for statistical analysis. Normality of all data samples was first checked by means of the Shapiro-Wilk test. When parametric analysis was possible, the Student *t* test for paired data was used for the comparison between preoperative and postoperative data, and the Student *t* test for unpaired data was performed to compare outcomes between specific groups (explanted vs. nonexplanted, mechanical vs. femtosecond).

When parametric analysis was not possible, the Wilcoxon rank-sum test was applied to assess the significance of differences between preoperative and postoperative data and the Mann-Whitney test was performed for the comparison between specific groups, using the same level of significance in all cases ($P < 0.05$).

Correlation coefficients (Pearson or Spearman depending if normality condition could be assumed) were used to assess the correlation between different variables. Finally, efficacy index was calculated as the ratio of the postoperative UCVA to the preoperative best-corrected visual acuity, and safety index was calculated as the ratio of the postoperative best-corrected visual acuity to the preoperative best-corrected visual acuity.

Table 2. Implantation Nomogram Used for KeraRings in this Study: Segment Distribution and Thickness Were Selected According to the Area of Ectasia and Spherical Equivalent

Spherical Equivalent (D)	All Ectasia Is Limited to One Half of the Cornea	75% of the Ectasia in One Half of the Cornea and 25% Situated in the Other Half	Two Thirds of the Ectatic Area in One Half of the Cornea and One Third in the Other Half	Ectasia is Distributed Evenly in Both Corneal Halves
$>-10\ \text{D}$	25/35	25/35	30/35	35/35
$-8\ \text{to}\ -10\ \text{D}$	20/30	20/30	25/30	30/30
$-6\ \text{to}\ -8\ \text{D}$	15/25	15/25	20/25	25/25
$-2\ \text{to}\ -6\ \text{D}$	0/20	0/20	15/20	20/20

D = diopters.

For defining the distribution of the ectasia, the cornea was divided into 2 halves using the steepest meridian as axis of separation, for example, 25/35 = upper segment thickness/lower segment thickness (0.25 mm/0.35 mm).

KeraRings; Mediphacos, Belo Horizonte, Brazil.

Table 3. Summary of the Refractive Outcomes during Follow-up

Parameter (Range)	Preoperative	3 Mos	6 Mos	12 Mos	24 Mos	P Value (Preoperative to 6 Mos)
UCVA	0.25±0.17 (0.05–0.60)	0.25±0.17 (0.05–0.60)	0.34±0.22 (0.05–0.80)	0.28±0.19 (0.05–0.70)	0.35±0.21 (0.05–0.80)	0.17
Sphere (D)	−2.10±3.37 (−13.00 to +3.50)	−1.17±3.72 (−12.50 to +5.00)	−1.58±4.51 (−14.00 to +5.00)	−2.55±5.11 (−13.00 to +9.00)	−2.64±5.46 (−15.00 to +3.00)	0.28
Cylinder (D)	−3.47±1.97 (−8.00 to 0.00)	−2.34±1.58 (−5.00 to 0.00)	−2.64±1.12 (−4.50 to −1.00)	−2.69±1.26 (−5.00 to −1.00)	−1.91±1.45 (−5.00 to 0.00)	0.05
SE (D)	−3.84±3.66 (−16.00 to +3.00)	−2.35±3.58 (−12.50 to +3.00)	−2.91±4.59 (−16.00 to +3.00)	−3.89±5.15 (−14.50 to +7.00)	−3.60±5.66 (−16.50 to +3.00)	0.17
BSCVA	0.48±0.24 (0.05–0.80)	0.52±0.23 (0.05–1.00)	0.61±0.30 (0.15–1.20)	0.55±0.21 (0.15–0.80)	0.54±0.27 (0.10–1.00)	0.02
Efficacy	—	0.67±0.66 (0.08–3.33)	0.75±0.60 (0.05–2.67)	0.86±0.86 (0.05–3.33)	1.09±0.87 (0.05–3.33)	—
Safety	—	1.40±1.26 (0.33–6.00)	1.80±1.44 (0.71–5.33)	2.01±1.92 (0.43–8.00)	1.71±1.03 (0.63–4.00)	—
No. of eyes	34	23	18	20	15	

BSCVA = best spectacle-corrected visual acuity; D = diopters; SE = spherical equivalent; UCVA = uncorrected visual acuity.

Ranges are shown in parentheses below each mean value. All patients completed a follow-up of at least 12 mos. During the first year of follow-up, no dropouts were found.

Results

A total of 34 eyes of 25 patients with a mean age of 37.27±9.27 years (range, 20–59 years) were included. Eleven patients were female (44%), and 14 patients were male (56%). There were an equal number of right and left eyes (17). Preoperatively, the location of the iatrogenic cone was central in 10 eyes (29.4%), inferior in 21 eyes (61.8%), and inferotemporal in 3 eyes (8.8%). Opacity of the cone area was observed in only 3 eyes (8.8%). According to the Amsler–Krumeich grading system,²⁹ 22 eyes had a cone grade I (64.7%), 6 eyes had grade II (17.6%), 4 eyes had grade III (11.8%), and 2 eyes had grade IV (5.9%). In regard to the corneal aberrations and according to the Alió–Shabayek grading system,²⁷ 9 eyes had a cone grade I (50%), 6 eyes had grade II (33.3%), 2 eyes had grade III (11.1%), and only 1 eye had grade IV (5.6%). In 5 eyes, corneal cross-linking treatment was applied after a 12-month follow-up. This kind of treatment was performed only if a significant regression of the corneal flattening and refractive correction achieved with the ICRS was observed. In these cases, data from the post-corneal cross-linking visits were not included to avoid biasing the final outcomes.

Refractive Outcomes

Refractive outcomes are summarized in Table 3. At 6 months postoperatively, a mean reduction of 0.93 diopters (D) in the SE was observed. This refractive change did not reach statistical significance ($P = 0.17$, Wilcoxon test). From 6 to 24 months, a nonstatistically significant increase was observed in this parameter ($P = 0.33$; Wilcoxon test). In regard to manifest cylinder, a decrease in the limit of statistical significance was found at 6 months (mean change = 0.83 D; $P = 0.05$; Student *t* test for paired data), with an additional significant reduction in the period from 6 to 24 months (mean change = 0.73 D; $P = 0.04$; Student *t* test for paired data). A nonsignificant reduction of 0.52 D in sphere was also found at 6 months ($P = 0.28$; Wilcoxon test), with a small but insignificant regression of the achieved correction during the rest of follow-up ($P = 1.00$; Wilcoxon test).

No statistically significant changes in UCVA were observed during the follow-up ($P = 0.17$, Wilcoxon test). Best spectacle-

corrected visual acuity increased significantly at 6 months ($P = 0.02$, Wilcoxon test), with no significant changes during the rest of follow-up ($P = 0.50$, Wilcoxon test). At 6 months, 38.89% of eyes gained 2 or more lines of BSCVA, and this percentage increased to 60% at 24 months (Fig 1). Losses of lines of BSCVA were observed in 4 eyes (22.22%) at 6 months and in 3 eyes (20%) at 24 months (Fig 1). One eye with a loss of BSCVA developed a significant corticonuclear cataract during the follow-up (cataract surgery 12 months after the ring segment implantation). In 2 additional cases with a best-corrected visual loss, segment ring explantation was performed because of the poor postoperative visual outcome achieved.

Mean efficacy and safety indexes at 6 months were 0.75±0.60 (range, 0.05–2.67) and 1.80±1.44 (range, 0.71–5.33), respectively. There was an improvement of both parameters between months 6 and 12, although with no statistical significance (efficacy $P = 0.25$; safety $P = 0.74$; Wilcoxon test) (Table 1).

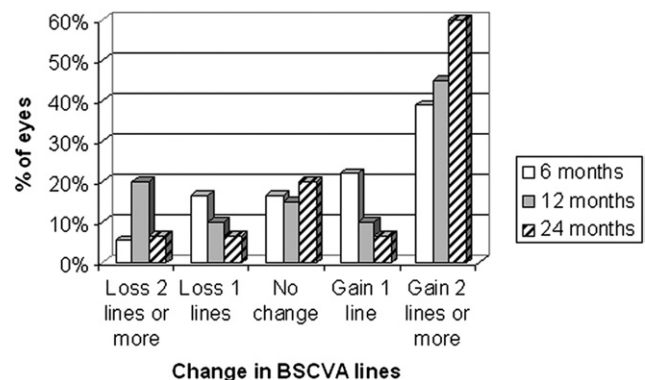


Figure 1. Changes in lines of BSCVA after ICRS implantation; 38.89% of eyes gained ≥2 lines of BSCVA at 6 months after surgery, and this percentage increased to 60% at 24 months. BSCVA = best spectacle-corrected visual acuity; ICRS = intracorneal ring segments.

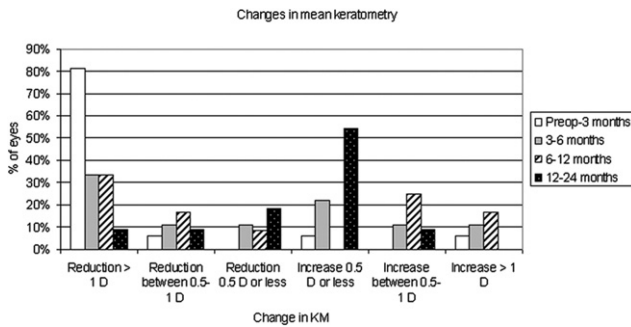


Figure 2. Analysis of changes in mean KM in different periods of the follow-up. At 3 months a reduction in KM was observed in 87.5% of eyes, whereas at 24 months this percentage decreased to 36.36%. D = diopters; KM = mean corneal power in the 3-mm zone.

Corneal Changes

A mean significant reduction of 1.54 D in mean keratometry was found at 6 months postoperatively ($P < 0.01$; Student *t* test for paired data) (preoperative: 45.76 ± 6.03 D vs. 6 months: 44.22 ± 5.06 D). A regression of the achieved central flattening was observed during the rest of the follow-up, but changes were not statistically significant ($P = 0.73$; Student *t* test for paired data) (6 months 44.22 ± 5.06 D vs. 24 months 45.96 ± 7.78 D). This finding was consistent with the decrease observed in the percentage of patients with a reduction in mean keratometry during the follow-up (Fig 2). At 3 months an increase in KM was observed in only 12.5% of eyes, whereas at 24 months this percentage increased to 63.64%.

No statistically significant changes were observed in any CSO topographic parameter during the follow-up, except for asphericity over a 4.5-mm diameter at 6 months, which became more negative ($P = 0.01$, Student *t* test for paired data) (Table 4). It means that the anterior corneal surface became more prolate after the ICRS implantation. In addition, there was a reduction in the ISAI, AST3, AST6, apical keratometry, and ACG, but changes did not reach statistical significance probably because of the small sample size and the high variability of these parameters. Finally, a statistically significant correlation was found between postoperative BSCVA at 6 months and the ISAI index ($r = -0.83$, $P = 0.01$; Spearman correlation coefficient).

Corneal Aberrations of the Anterior Surface

A detailed report of the corneal aberrometric outcomes is shown in Table 5. At 6 months only a statistically significant reduction was found in coma-like RMS ($P = 0.03$, Wilcoxon test). RMS values for total, astigmatism, and primary coma aberrations were also reduced, but changes did not reach statistical significance (Table 5). A tendency to postoperative negative primary spherical aberration was also observed (Table 5), which was consistent with the significant negativization of corneal asphericity. In addition, a nonsignificant increase in higher-order residual and spherical-like RMS was found ($P = 0.48$ and $P = 0.26$, respectively, Wilcoxon test). Preoperative primary spherical aberration Zernike term ($r = 0.71$, $P = 0.04$), coma ($r = -0.92$, $P < 0.01$) and coma-like RMS ($r = -0.92$, $P < 0.01$) were significantly correlated with postoperative BSCVA at 6 months (Spearman correlation coefficient).

Table 6 shows a comparative analysis of the preoperative and early postoperative aberrometric outcomes in 2 groups of eyes: those implanted with ring segments using the mechanical dissection for corneal tunnelization (20 eyes) and those implanted using the femtosecond laser technology (14 eyes). As shown in Table 6, the initial postoperative higher-order residual, spherical-like, and coma-like RMS values were higher in the group of eyes receiving the mechanical procedure, but differences reached statistical significance for only spherical-like RMS ($P = 0.03$, Mann-Whitney test). In addition, there was a nonstatistically significant trend of primary spherical aberration to negative values in the group of eyes receiving the mechanical procedure.

Figure 3 shows a comparative analysis of the initial postoperative aberrometric data in eyes implanted with Intacs (24 eyes) and eyes implanted with KeraRings (10 eyes). No statistically significant differences were found between both groups of eyes preoperatively (all $P > 0.20$, Mann-Whitney test) and at 1 month after surgery (all $P > 0.24$, Mann-Whitney test).

Complications

Segment ring explantation was performed in 6 eyes (17.6%). Three eyes were explanted because of significant postoperative visual problems (loss of BSCVA and patient dissatisfaction with the visual quality achieved). In the remaining 3 eyes, explantation was performed because of ring segment extrusion or migration problems (all of them receiving the mechanical procedure, mean corneal depth of implantation 381.33 ± 22.71 μm). Five of the 6 explanted ring segments were Intacs, and only 1 ring segment was KeraRing. In addition, in 2 cases (5.9%) ring segment reposition

Table 4. Summary of Changes in Topographic Corneal Parameters Provided by the Costruzione Strumenti Oftalmici System

Parameter	Preoperative	3 Mos	6 Mos	12 Mos	24 Mos	P Value (Preoperative to 6 Mos)
ISAI (D)	11.52 ± 7.25	6.52 ± 8.06	8.52 ± 7.92	5.40 ± 9.41	5.08 ± 9.43	0.16
AST3 (D)	5.18 ± 2.36	3.02 ± 1.12	3.42 ± 2.41	2.94 ± 2.04	3.61 ± 3.20	0.15
AST6 (D)	3.97 ± 1.74	2.70 ± 0.82	3.02 ± 1.56	2.21 ± 1.47	3.20 ± 1.24	0.43
Q45	-1.78 ± 2.28	-3.12 ± 3.59	-3.33 ± 3.40	-1.28 ± 4.31	-3.68 ± 3.13	0.02
Q8	-0.42 ± 1.29	-0.33 ± 1.05	-1.03 ± 1.66	0.98 ± 3.69	-1.35 ± 1.44	0.25
AK (D)	65.98 ± 14.04	69.90 ± 13.10	63.36 ± 13.29	62.73 ± 9.87	65.52 ± 12.52	0.58
ACG (mm/D)	10.37 ± 7.93	9.37 ± 3.78	10.35 ± 7.60	9.87 ± 5.10	9.02 ± 6.87	0.78
No. of eyes	15	10	10	12	6	

ACG = apical curvature gradient; AK = apical keratometry; AST3 = corneal astigmatism in the 3-mm zone; AST6 = corneal astigmatism in the 6-mm zone; CSO = Costruzione Strumenti Oftalmici; D = diopters; ISAI = inferosuperior asymmetry index; Q45 = mean asphericity for a corneal area of 4.5-mm diameter; Q8 = mean asphericity for a corneal area of 8-mm diameter.

All patients completed a follow-up of at least 12 mos. During the first year of follow-up, no dropouts were found.

Table 5. Summary of the Corneal Aberrometric Outcomes

Parameter	Preoperative	3 Mos	6 Mos	12 Mos	24 Mos	P Value (Preoperative to 6 Mos)
Total RMS (μm)	17.20 \pm 17.59 (3.14–67.04)	12.12 \pm 9.80 (2.73–29.25)	14.23 \pm 8.92 (2.41–26.33)	10.87 \pm 7.73 (2.65–24.39)	10.10 \pm 4.83 (5.33–18.16)	1.00
RMS Astigmatism (μm)	2.89 \pm 2.06 (0.41–7.08)	2.39 \pm 0.91 (0.89–3.78)	2.30 \pm 0.73 (0.53–3.32)	2.00 \pm 0.83 (0.56–3.55)	2.51 \pm 1.13 (0.55–3.89)	0.89
Primary coma RMS (μm)	3.17 \pm 1.94 (0.69–7.84)	2.03 \pm 1.22 (0.59–4.03)	2.35 \pm 1.75 (0.46–6.30)	2.31 \pm 1.18 (1.06–4.84)	2.08 \pm 1.16 (0.77–3.73)	0.09
Z_4^0 (μm)	0.02 \pm 0.96 (–2.29 to 1.52)	0.02 \pm 0.70 (–1.14 to 1.30)	–0.01 \pm 0.70 (–1.09 to 1.32)	–0.85 \pm 1.36 (–4.59 to 0.62)	–0.90 \pm 0.97 (–2.71 to 0.00)	0.67
Residual RMS (μm)	1.60 \pm 0.67 (0.75–2.87)	1.80 \pm 0.67 (0.91–3.13)	1.96 \pm 0.70 (0.77–3.04)	1.98 \pm 0.65 (1.00–2.91)	1.98 \pm 0.61 (1.12–2.91)	0.48
Spherical-like RMS (μm)	1.28 \pm 0.60 (0.47–2.49)	1.07 \pm 0.51 (0.63–2.14)	1.36 \pm 0.51 (0.64–2.13)	1.59 \pm 1.16 (0.55–5.05)	1.61 \pm 0.91 (0.38–3.20)	0.26
Coma-like RMS (μm)	3.52 \pm 1.83 (1.19–7.95)	2.60 \pm 1.22 (1.36–4.74)	2.95 \pm 1.63 (0.81–6.58)	2.74 \pm 1.14 (1.46–5.09)	2.67 \pm 1.04 (1.71–4.35)	0.03
No. of eyes ^a	15	10	10	12	6	

RMS = root mean square. Definitions of each kind of corneal aberration: primary coma, Zernike terms $Z_3^{\pm 1}$; primary spherical aberration, Zernike term Z_4^0 ; residual aberrations, all Zernike terms except $Z_3^{\pm 1}$ and Z_4^0 ; spherical-like aberrations, Zernike terms fourth and sixth order; coma-like aberrations, Zernike terms third and fifth order.

Ranges are given in parentheses below each mean value.

^aAll patients completed a follow-up of at least 12 months. During the first year of follow-up no dropouts were found.

was necessary to achieve a greater effect. One of these repositioned ring segments was finally explanted because of the significant degradation of visual quality. No severe complications such as infections occurred. Ring extrusion was observed in only 1 eye at 6 months, and it was finally explanted. Mild channel deposits were observed in 4 eyes implanted with Intacs at 12 months.

Figure 4 shows a comparison of the preoperative refractive data of explanted (6 eyes) and nonexplanted eyes (28 eyes). Mean sphere and cylinder were higher preoperatively in the nonexplanted group, but differences did not reach statistical significance (all $P > 0.17$, Mann–Whitney test) (Fig 4). Mean keratometry was 46.42 ± 6.18 D in the nonexplanted group and 42.16 ± 3.75 D in the explanted group. Differences in this parameter were not statistically significant ($P = 0.15$, Mann–Whitney test).

Because all the explanted cases were examined with the CSO topography system, a comparative analysis of the aberrometric and curvature parameters provided by this device was feasible. No statistically significant differences were found between groups in

apical keratometry, Q45, Q8, AST3, AST6, and ISAI (all $P > 0.16$, Mann–Whitney test). However, the ACG was significantly higher in the group of explanted eyes (7.89 ± 4.89 nonexplanted vs. 19.04 ± 11.14 explanted; $P = 0.03$, Mann–Whitney test) (Fig 5). In regard to corneal aberrations, all the aberrometric coefficients were on average higher in the group of explanted eyes (Fig 6), but the differences between groups did not reach statistical significance probably because of the small sample size (only 6 eyes were explanted) ($P = 0.14$, Mann–Whitney test).

Discussion

The insertion of extra material (ring segments) in the deep stroma induces a modification of the corneal curvature and corneal shape.²⁵ These mid-peripheral implants in a healthy cornea generate a central flattening because of the stromal

Table 6. Summary of Early Aberrometric Outcomes (1 Month Postoperative) in 2 Groups of Eyes: Those Implanted with Ring Segments Using the Mechanical Dissection for Corneal Tunnelization and Those Implanted Using Femtosecond Laser Technology

Parameter	Mechanical		IntraLase		P Value	
	Preoperative	1 mo Postoperative	Preoperative	1 mo Postoperative	Preoperative	Postoperative
Total RMS	17.30 \pm 18.14	17.62 \pm 17.91	15.94 \pm 20.60	13.22 \pm 9.57	0.30	0.56
RMS astigmatism	2.61 \pm 2.61	2.19 \pm 2.18	3.26 \pm 2.05	2.18 \pm 0.88	0.96	0.56
Primary coma RMS	3.53 \pm 2.57	2.69 \pm 0.97	2.75 \pm 1.56	2.50 \pm 1.50	0.30	0.52
Primary spherical aberration	–0.19 \pm 0.80	–0.19 \pm 2.11	–0.02 \pm 1.15	0.03 \pm 0.62	0.68	0.91
Residual RMS	1.61 \pm 0.67	3.05 \pm 1.95	1.59 \pm 0.63	1.88 \pm 0.94	0.28	0.20
Spherical-like RMS	1.19 \pm 1.35	2.69 \pm 1.63	1.35 \pm 0.69	1.21 \pm 0.41	0.26	0.03
Coma-like RMS	3.87 \pm 2.44	3.61 \pm 1.46	3.18 \pm 1.36	2.96 \pm 1.68	0.44	0.41

RMS = root mean square.

Comparative analysis of preoperative and early postoperative data is shown for each group.

Definitions of each kind of corneal aberration: primary coma, Zernike terms $Z_3^{\pm 1}$; primary spherical aberration, Zernike term Z_4^0 ; residual aberrations, all Zernike terms except $Z_3^{\pm 1}$ and Z_4^0 ; spherical-like aberrations, Zernike terms fourth and sixth order; coma-like aberrations, Zernike terms third and fifth order.

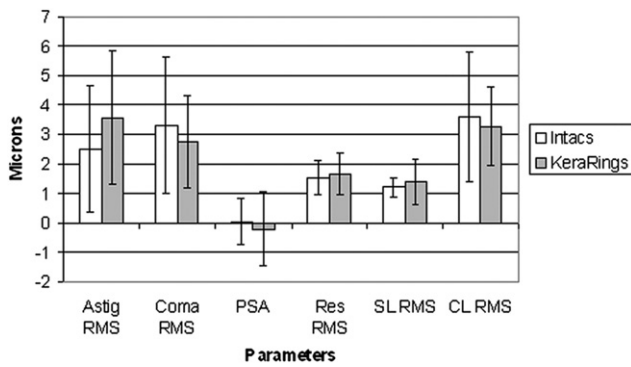


Figure 3. Comparative analysis of the initial postoperative aberrometric data in the group of eyes implanted with Intacs (24) (Addition Technology, Inc., Fremont, CA) and the group implanted with KeraRings (10) (Mediphacos, Belo Horizonte, Brazil). No statistically significant differences were found between both groups of eyes in any preoperative and 1-month postoperative corneal aberrometric parameter. Astig = astigmatism; CL = coma-like; PSA = primary spherical aberration; Res = residual; RMS = root mean square; SL = spherical-like. Definitions of each kind of corneal aberration: primary coma, Zernike terms $Z_3^{\pm 1}$; primary spherical aberration, Zernike term Z_4^0 ; residual aberrations, all Zernike terms except $Z_3^{\pm 1}$ and Z_4^0 ; spherical-like aberrations, Zernike terms fourth and sixth order; coma-like aberrations, Zernike terms third and fifth order.

collagen structure.²⁵ The magnitude of this flattening effect is in direct proportion to the thickness of the implant and in inverse proportion to its diameter.²⁵ This corneal flattening induced by the ICRS could be especially useful in the ectatic corneal disease for minimizing the corneal protrusion and consequently the refractive error. However, it should be considered that the stromal structure is altered in the ectatic cornea, with a nonorthogonal lamellar architecture.^{30,31} Studies are necessary to define with precision the effect of this kind of implant in these weak corneas and how it can be predicted. In the specific case of the post-LASIK ectasia, the corneal structure is weakened by the laser tissue ablation, which breaks the balance between corneal biomechanics and intraocular pressure. However, it still remains unknown if the lamellar configuration in these specific cases is also altered. The present study attempts to characterize the refractive and corneal aberrometric effect of ICRS in this specific group of ectatic corneas. These changes would be the result of biomechanical modifications produced by the implants as a consequence of changes induced in the distribution of the corneal peripheral lamellae.

All the published studies on ICRS implantation for the management of post-LASIK ectasia are case reports or small series including a limited number of cases because of the complexity of finding such cases in clinical practice.^{13,17–24} In this study, we collected data retrospectively from 2 ophthalmologic centers to achieve a large sample of cases, and we analyzed the refractive and aberrometric changes after the ICRS implantation during a 24-month follow-up. To the best of our knowledge, this study includes the largest reported series of cases of post-LASIK ectasia implanted with ICRS, 34 eyes.

Nonsignificant changes were found in sphere (mean change at 6 months, 0.52 D) and SE (mean change at 6

months, 0.93 D) after surgery, whereas a significant progressive reduction in cylinder was observed (mean change at 6 months, 0.83 D; mean change at 24 months, 1.56 D). On the contrary, other authors reported significant reductions in SE with ICRS.^{18,22} An explanation for this difference could be the great variability in the preoperative SE observed in our sample, with a mean standard deviation of 3.66 D. In addition, a nonsignificant regression of the sphere and SE correction was observed in the period going from month 6 to month 24, suggesting that the ICRS did not stop the progression of the corneal ectasia. The significant astigmatic reduction found in our study supports the findings of previous studies.^{19,20}

No significant changes were observed in UCVA during the follow-up, whereas a significant improvement in BSCVA was found. This best-corrected visual improvement was also reported in all previous series of post-LASIK ectasia with ICRS,^{13,17–24} which confirms the adequate visual outcome provided by these implants in these ectatic corneas. In the current study, 38.89% of eyes gained 2 or more lines of BSCVA at 6 months after surgery, whereas this percentage increased to 60% at 24 months. Safety index in all visits was excellent (values >1), whereas the efficacy index was limited in the initial postoperative period, achieving values of ~1 at 12 and 24 months postoperatively.

In regard to changes in corneal curvature, a significant central corneal flattening was observed in the initial postoperative period (mean change, 1.54 D), with a posterior nonsignificant regression of this flattening effect (mean change, 1.74 D). This regression was consistent with the increase in myopia observed in the final part of the follow-up. However, Kymionis et al¹⁸ found that mean keratometry remained stable postoperatively during a 5-year follow-up in a sample of 8 eyes. This difference in the keratometric evolution between both studies could be explained in part because significantly different samples of cases were evaluated. Mean preoperative keratometry was 45.76 D (range, 32.65–59.84 D) in our study, whereas it was 41.29 D (range, 37.79–46.15 D) in the study of Kymionis et al.¹⁸ More moderate and advanced cases were included in our study,

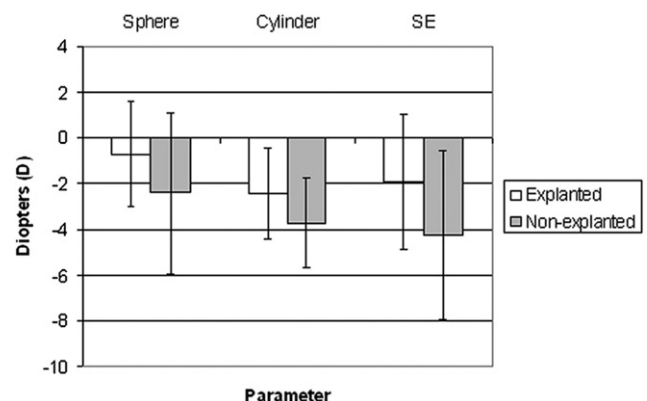


Figure 4. Comparison of preoperative refractive data in explanted and nonexplanted eyes. Mean sphere and cylinder were higher preoperatively in the nonexplanted eyes, but differences did not reach statistical significance. SE = spherical equivalent.

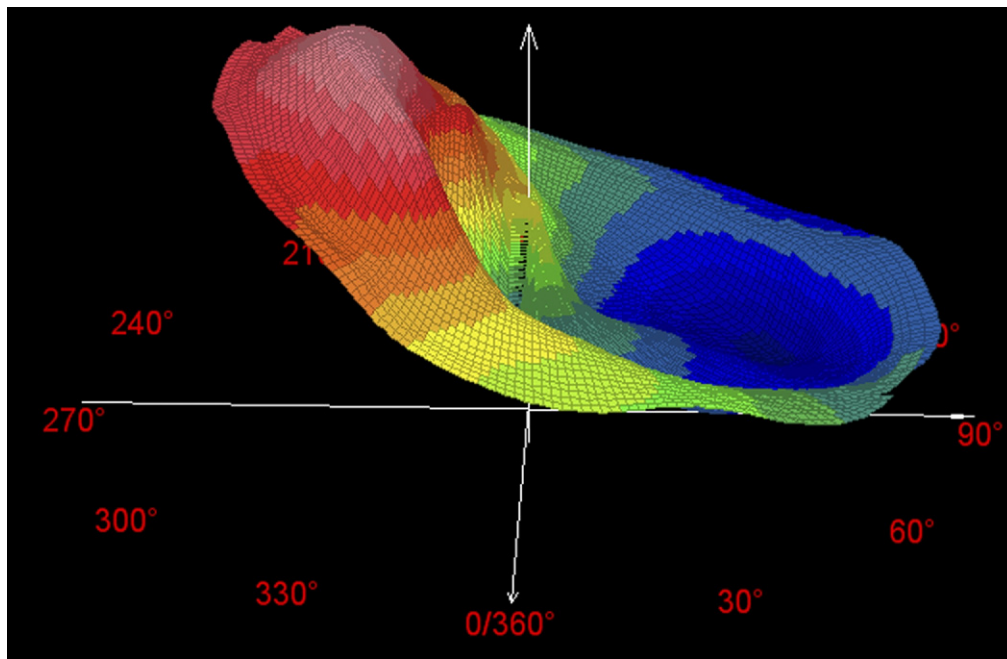


Figure 5. Three-dimensional preoperative corneal profile of a cornea in which ring segments were explanted. Preoperative apical gradient curvature was extremely high, 34.53 D. D = diopters.

and the ICRS effect probably was more unstable and unpredictable in these specific cases.

To the best of our knowledge, this is the first report on anterior corneal aberrometric outcomes after ICRS implantation in corneas with post-LASIK ectasia. Anterior corneal aberrometric analysis is an important tool in clinical practice for evaluating the ocular optical quality. It should be considered that the first refractive interface (air–cornea) is the most important contributor to the total power of the eye because of the large difference in refractive index existing at

this point. In highly aberrated corneas, such as in post-LASIK ectasia, the corneal aberrations of the anterior corneal surface are the most important source of optical errors in the eye. In the current study, we found that coma-like aberrations were significantly reduced with the implantation of ICRS. In addition, a nonsignificant reduction in primary coma was also observed. These modifications in the magnitude of coma-like aberrations were consistent with the postoperative improvement in BSCVA and the postoperative reduction in the inferosuperior asymmetry (although this change was not statistically significant). The primary and secondary comatic errors (the central Zernike terms from the third and fifth order, included in the coma-like RMS) have been demonstrated to have a negative impact on visual acuity because of the kind of optical blur that they induce.³² These findings are consistent with those reported by Alió and Shabayek,²⁹ who also found a reduction of coma-like aberrations in keratoconic corneas implanted with KeraRings using the femtosecond technology, as well as a significant improvement in BSCVA. In addition to coma-like aberrations, a nonsignificant postoperative trend to more negative values of primary spherical aberration was observed. This finding was consistent with the negativization of the central corneal asphericity that was also observed.

No significant differences in corneal aberrometric outcomes between Intacs and KeraRings were found. However, there was a limitation for this analysis that should be considered: The sample of cases implanted with each ring segment type was small. On the contrary, the surgical technique used for ring segment implantation seemed to have an important role in the final outcome. A significantly higher magnitude of higher-order residual, coma-like, and spherical-like aberrations were found in those eyes that underwent

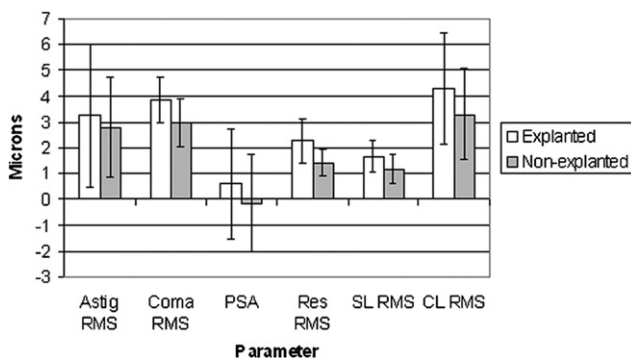


Figure 6. Comparative analysis of corneal aberrometric parameters in explanted and nonexplanted eyes. All aberrometric coefficients were on average higher in the group of explanted eyes, but differences did not reach statistical significance. Astig = astigmatism; CL = coma-like; PSA = primary spherical aberration; Res = residual; RMS = root mean square; SL = spherical-like. Definitions of each kind of corneal aberration: primary coma, Zernike terms $Z_3^{\pm 1}$; primary spherical aberration, Zernike term Z_4^0 ; residual aberrations, all Zernike terms except $Z_3^{\pm 1}$ and Z_4^0 ; spherical-like aberrations, Zernike terms fourth and sixth order; coma-like aberrations, Zernike terms third and fifth order.

operation with the mechanical procedure in the initial postoperative period. Therefore, it seems that the femtosecond technology is a better surgical procedure for implanting ICRS in post-LASIK ectatic corneas. The mechanical tunnelization may lack sufficient precision, and this may affect corneal aberrations leading to reduced optical performance. There are no previous studies comparing the aberrometric outcomes in eyes implanted with ICRS using the mechanical and the femtosecond-assisted procedures. Previously, only refractive and visual outcomes were compared between surgical techniques, and no statistically significant differences were observed in corneas with keratoconus and post-LASIK ectasia.³³

We also studied whether preoperative aberrations could be used as a predictor for a good or bad visual prognosis. Preoperative primary coma and coma-like aberrations were inversely correlated with postoperative BSCVA. It seems that the presence of large corneal asymmetries inducing comatic aberrations is a limiting factor of the ICRS effect. In addition, corneas in which rings were explanted had on average higher preoperative values for all aberrometric coefficients. However, these aberrometric differences between explanted and nonexplanted eyes did not reach statistical significance. As happened with the comparison between Intacs and KeraRings, there was a limitation in this analysis because of the small sample of eyes compared. The ACG that defines the progression of curvature from the apex to the periphery (changes in diopters of curvature per millimeter) was significantly higher in the group of explanted eyes (Fig 5). Therefore, it seems that ectatic corneas with high irregularity and a pronounced conic protrusion are poor candidates for ICRS. This type of corneal configuration could be associated to a specific corneal structure limiting the ring segment effect and providing poorer results. It has been demonstrated that the keratoconic corneal structure is different compared with normal corneas with regions of more highly aligned collagen intermixed with regions in which there is little aligned collagen, and then a distortion of the orthogonal lamellar matrix.^{30,31} In these cases with a significantly conic corneal protrusion, the distribution of lamellae in the cone area is highly irregular with a poor or unpredictable response to peripheral addition of material. In any case, future studies are required to understand how the configuration of ectatic corneal structure could influence the mechanism of action of the ICRS.

In conclusion, ICRS implantation, with Intacs or KeraRings, is a useful option for the treatment of corneal irregularity and astigmatism in post-LASIK corneal ectasia. Coma-like aberrations are significantly reduced with these implants, and a significant improvement in BSCVA is achieved. Anterior corneal aberrometry is a useful tool for achieving a better understanding of ICRS outcomes and as a screening factor for avoiding the implantation in those cases with poorer visual prognosis, eyes with high preoperative levels of corneal comatic aberrations. In addition, it seems that the use of the mechanical procedure for the implantation of ICRS limits the potential aberrometric correction of these implants, the procedure itself generating new aberrations.

The spherical correction and central flattening induced by ICRS are maintained during the initial postoperative

period, but a regression of these effects is observed 12 months after surgery. This indicates that this kind of implant did not stop the progression of corneal ectasia in all cases. In any case, longer follow-ups are required to corroborate this refractive and keratometric instability in the long-term. Corneal collagen cross-linking could be another treatment option in those patients in whom the progression of the ectasia continues. It has been stated that corneal cross-linking is a therapeutic mean to arrest and partially reverse the progression of LASIK-induced iatrogenic keratectasia.³⁴ The combination of both techniques could have an important potential in post-LASIK ectasia treatment, and future studies should address this issue.

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